REMARKS

Claims 1-23 and 49-54 were pending at the time of the Office action. Claims 49 and 54 are amended to correct minor clerical errors. Claims 55-62 are newly added. No new matter is added. As such, claims 1-23 and 49-62 are pending in the application.

Telephone Interview

Applicants express appreciation to the Examiner (Mr. Gray) for the courtesy of the telephone interview held on March 17, 2009, with Applicants' representative Norman Lee (Reg. No. 58,941). In the interview, claim 1 was discussed. In addition, the following references were discussed: Barry ("Barry," U.S. Patent Application Publication No. 2002/0077592) and Tu et al. ("Tu," U.S. Patent No. 6,053,913). More specifically, Applicants' representative explained that Tu did not disclose or suggest features of claim 1. In addition, Applicants' representative explained that combining Barry and Tu in the manner proposed by the Examiner would render Barry's temperature sensor unsatisfactory for its intended purpose of regulating a heat treatment of an aneurysm.

The Examiner indicated that he understood the above explanation, and it is believed that the explanation overcomes the rejection based on Barry in view of Tu. No agreement was reached on claim 1. Further, Applicants' representative and the Examiner discussed other features of this application that further emphasize distinctions of the claimed embodiments over the cited art.

Claim Rejections Under 35 U.S.C. 103

On page 3 of the Office action, claims 1-11, 14-23 and 49-54 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Tu. On page 5 of the Office action, claims 12-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Tu in further view of Silver ("Silver," U.S. Patent No. 6,442,413). On page 5 of the Office

action, claims 4 and 19-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Tu.

The above rejections are respectfully traversed.

As previously presented, claim 1 recites:

> A method for mitigating restenosis at a trauma site at which a stent is located within the vasculature comprising:
>
> positioning a catheter adjacent the trauma site;
>
> extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent; and
>
> delivering a restenosis mitigating drug to the trauma site through the catheter
>
> wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor. (Emphasis added.)

As acknowledged by the Examiner on page 4 of the Office action, Barry does not disclose "extending a sensor . . . through the stent to a position located outside of the catheter and outside of the stent[.]"

However, the Examiner alleges that Tu discloses the noted features. Further, the Examiner alleges that it would have been obvious to modify Barry per the cited disclosures of Tu.

Applicants respectfully traverse the above allegations.

As will be explained in more detail below, Applicants respectfully submit that Tu does not address distinctions of claim 1 over Barry. Moreover, for reasons similar to those previously explained in Applicants' Amendment of June 17, 2008, and in Applicants' Appeal Brief of November 5, 2008, the proposed combination of Barry and the alleged disclosure of Tu does not

render claim 1 *prima facie* obvious because this combination would render the invention of Barry unsatisfactory for its intended purpose. (See MPEP § 2143.01.)

First, Tu does not address distinctions of claim 1 over Barry. As previously noted, claim 1 recites, in a relevant portion, "extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent[.]" (Emphasis added.)

Tu does not disclose or suggest "extending a sensor through a lumen in the catheter . . ." as recited in claim 1. (Emphasis added.) Tu discloses that temperature sensor 27 is relayed through temperature sensing wire 28. (See Tu, col. 5, lines 20-22.) Tu does not disclose or suggest that either sensor 27 or wire 28 is extended through a lumen in the catheter.

Tu discloses that wire 28 passes to an external temperature control mechanism through outlet connector 6. (See Tu, col. 7, lines 14-17.) The disclosure of wire 28 passing through outlet connector is consistent with the "overall view" of FIG. 2. (See Tu, FIG. 2.) The "overall view" of FIG. 2 does not explicitly show the location of the wire 28 with respect to catheter shaft 9.

However, any contention that Tu's FIG. 2 somehow illustrates that wire 28 extends through a lumen in catheter shaft 9 would be inconsistent what is explicitly illustrated in the cross-sectional view of FIG. 3. For example, FIG. 3 explicitly shows that wire 28 does not extend through inflation lumen 13 of catheter shaft 9. Rather, according to FIG. 3, wire 28 extends outside of inflation lumen 13 and outside of catheter shaft 9.

The discrepancy between the overall view of FIG. 2 and the cross-sectional view of FIG. 3 with regards to wire 28 is similar to another discrepancy between what is illustrated in the same figures with regards to electrical conductor 29. Similar to wire 28, conductor 29 also is apparently shown in FIG. 2 as passing through outlet connector 6. The "overall view" of FIG. 2 does not explicitly show the location of the conductor 29 with respect to catheter shaft 9.

However, any contention that Tu's FIG. 2 somehow illustrates that conductor 29 extends through a lumen in catheter shaft 9 would be inconsistent what is explicitly illustrated in the cross-sectional view of FIG. 3. For example, FIG. 3 explicitly shows that conductor 29 does not extend through inflation lumen 13 of catheter shaft 9. Rather, according to FIG. 3, conductor 29 is located outside of inflation lumen 13 and outside of catheter shaft 9. Indeed, Tu teaches that conductor 29 is connected to stent 11, which is wrapped around (and is, therefore, located outside of) the catheter shaft. (See Tu, col. 6, line 1, and col. 7, lines 30-31.) Because Teaches that conductor 29 is connected to stent 11 and because stent 11 wraps around the catheter shaft, conductor 29 is also outside of the catheter shaft (and, therefore, outside of, the catheter lumen).

Therefore, Tu does not disclose or suggest "extending a sensor through a lumen in the catheter . . ." as recited in claim 1. (Emphasis added.)

Further, Tu does not disclose or suggest "extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent . . ." as recited in claim 1. (Emphasis added.)

Tu's FIG. 3 shows that temperature sensor 27 is inside the stent. Further, Tu discloses that sensor 27 is "disposed at close proximity of the deployed reversibly collapsible stent 11." (Tu, col. 7, lines 12-14). One skilled in the art would understand Tu as disclosing that sensor 27 is located in (or within) the stent.

For example, Tu is silent on the procedure by which the sensor 27 is positioned in a patient's body. However, Tu does describe a method by which the stented balloon catheter is inserted in the patient. (See Tu, col. 7, lines 51-60.) According to this method, the stented catheter is inserted to the stenosis location while the catheter is in a non-deployed state. Then, the balloon is deployed, thereby deploying the stent.

The illustration of temperature sensor 27 residing inside the stent (see Tu, FIG. 3) and the disclosure that sensor 27 is located at close proximity of the deployed stent (see Tu, col. 7, lines

12-14) strongly suggests that sensor 27 resides in the stent before deployment, during deployment, and after deployment.

As previously explained, Tu is silent on the procedure by which the sensor is inserted into the patient's body. However, Tu's description of the method by which the catheter is inserted (see Tu, col. 7, lines 51-60) suggests that the sensor 27 is already positioned in the stent 11 at the time the catheter is inserted to the stenosis location. Further, it suggests that, when the catheter is properly positioned and the balloon is deployed, the sensor 27 is carried with the stent 11. That is, the sensor 27 is moved with the stent 11 as the balloon is deployed. In moving with the stent, the sensor 27 must remain within the stent.

Therefore, Tu does not disclose or suggest "extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent . . ." as recited in claim 1. (Emphasis added.)

Because Tu does not disclose or suggest "extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent" and because Silver does not address distinctions of claim 1 over Barry in view of Tu, Applicants respectfully submit that claim 1 is patentable over the cited references.

Moreover, it was explained in Applicants' Amendment of June 17, 2008, and in Applicants' Appeal Brief of November 5, 2008, that the Examiner's proposed combination of Barry and Adair et al. ("Adair," U.S. Patent No. 6,211,904) did not render claim 1 *prima facie* obvious because this combination would render the invention of Barry unsatisfactory for its intended purpose of regulating the heat treatment of an aneurysm. (See MPEP § 2143.01.)

For reasons similar to those previously explained with respect to the combination of Barry and Adair, the proposed combination of Barry and the Examiner's understanding of Tu would also render the invention of Barry unsatisfactory for its intended purpose.

As explained with respect to the combination of Barry and Adair, Barry discloses that the heat treatment is provided by heating liquid 234 that is located inside of balloon 235. (See Paragraph [0088] and FIG. 14.) Heating the liquid induces thermal coagulation of aneurysmal wall 223. (See Paragraph [0089].) For accurately regulating the temperature of the liquid, a feedback control signal is required: this feedback control signal is provided by temperature sensor 255, which is positioned in the liquid. (See Paragraph [0089] and FIG. 14, which shows temperature sensor 255 as being located inside balloon 235.) Because stent 36 is also located inside balloon 235, the temperature sensor 255 is located inside both stent 35 and catheter 30.

Modifying Barry to require extending temperature sensor 255 through stent 36 to a position located outside of catheter 30 and outside of stent 36 would position the sensor outside of liquid 234. As such, the sensor would be rendered incapable of monitoring the temperature of liquid 234. Further, the sensor would be incapable of providing a feedback control signal for accurately regulating the heating of the liquid.

Because modifying the position of Barry's sensor, as proposed by the Examiner, would render the sensor incapable of monitoring the temperature of the liquid and providing an appropriate feedback control signal, claim 1 is further patentable over Barry in view of Tu.

At least for the reasons explained, claim 1 is patentable over the cited art.

Claims 2-23 and 49-51 depend, either directly or indirectly, from claim 1. At least for this reason, claims 2-23 and 49-51 are patentable over the cited art.

As previously presented, claim 52 recites;

> A method for mitigating restenosis at a site within a vasculature, the method comprising:
>
> positioning a stent at the site;
>
> positioning a catheter adjacent the site;

extending a sensor through the catheter and through the stent to a position located outside of the catheter and outside of the stent, while the stent is at the site; and

delivering infusion medium to the trauma site through the catheter;

wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or a chemical parameter sensor. (Emphasis added.)

At least for reasons similar to one or more reasons explained with respect to claim 1, claim 52 is patentable over the cited art.

Claims 53 and 54 depend directly from claim 52. At least for this reason, claims 53 and 54 are patentable over the cited art.

New Claims

New dependent claims 55-58 depend indirectly from claim 1. At least for this reason, new dependent claims 55-58 are patentable over the cited art.

Further, new claims 55-58 recite features that further emphasize distinctions as discussed above with regard to the proposed combination of Barry and Tu.

For example, new claim 55 recites: "wherein the sensor has a lengthwise dimension extending along a first direction" and "wherein positioning the catheter relative to the stent comprises positioning the catheter relative to the stent so that the stent is located between the outlet and the sensing element, relative to the first direction." (Emphasis added.)

New claim 56 recites: ". . . wherein extending the sensor to a position at which the sensing element is located on one side of and spaced from the stent comprises extending the sensor to a position at which the sensing element is located at the distal end of the stent." (Emphasis added.)

New claim 57 depends from claim 56 and recites ". . . wherein the stent further includes a proximal end opposite to the distal end of the stent."

New claim 58 recites: ". . . wherein extending the sensor through the lumen in the catheter and through the stent comprises extending the sensor through a proximal end of the stent and a distal end of the stent opposite the proximal end." (Emphasis added.)

Because the features of these claims further emphasize distinctions over the proposed combination of Barry and Tu, these claims are further patentable over the cited art.

New dependent claims 59-62 depend indirectly from claim 52. At least for this reason, new dependent claims 59-62 are patentable over the cited art.

For reasons similar to those explained above with respect to new claims 55-58, new claims 59-62 are further patentable over the cited art.

Concluding Remarks

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 3/19/09

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